UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

RIVKA REICHMANN,

Plaintiff,

-against-

WHIRLPOOL CORPORATION
and
KITCHENAID, INC.,

Defendants.

Case No. 2:16-cv-05151

Plaintiff's Memorandum of Law in Opposition to Defendants' Motion to Preclude Evidence and Opinions on Diffusion Tensor Imaging

Kenneth B. Goldblatt, Esq.
Goldblatt & Associates, P.C.
1846 East Main Street (Route 6)
Mohegan Lake, New York 10547
(914) 788-5000

Gabriel Posner, Esq.
Posner Law PLLC
270 Madison Avenue
Suite 1203
New York, New York 10016
(646) 546-5022

Counsel for Plaintiff

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Plaintiff Rivka Reichmann, by undersigned counsel, respectfully opposes the motion of defendants Whirlpool Corporation and KitchenAid, Inc. (together, "Whirlpool") to preclude plaintiff's diffusion tensor imaging ("DTI") evidence and related opinions and testimony.[1]

PRELIMINARY STATEMENT

Dozens of courts have held that diffusion tensor imaging is admissible into evidence to assess traumatic brain injury ("TBI") under *Daubert* and analogous state-law standards – precisely the evidence plaintiff offers here. There are thousands of peer-reviewed articles on the reliability of DTI, many addressing TBI specifically. Dr. Michael Lipton, plaintiff's neuro-radiology and DTI expert, is a leading authority on DTI and has published widely on the subject. In the declaration submitted herewith, Dr. Lipton explains his qualifications, his methods and their reliability, and cites extensive scientific literature in support thereof, as previously disclosed to Whirlpool in discovery. Whirlpool retained its own neuro-radiology expert for this litigation (Dr. Tanenbaum) yet did not submit an affidavit from him nor rely upon his report in support of its motion. Whirlpool's arguments go to the *weight*, not the *admissibility*, of plaintiff's DTI evidence.

In addition to reviewing plaintiff's DTI scan, Dr. Lipton performed a "differential diagnosis," in which he carefully reviewed plaintiff's medical history and the clinical context to rule out alternative explanations for plaintiff's DTI results. A differential diagnosis is standard practice medically – almost any medical test must be considered in light of the patient's reported symptoms, medical history, and clinical context – and differential diagnosis is well recognized as admissible into evidence. As Dr. Lipton explained, certain neurodegenerative diseases or other pathologies could hypothetically explain abnormally low anisotropy in the brain (the key result of plaintiff's DTI). Reviewing plaintiff's medical files, Dr. Lipton identified no reasonably plausible

[1] In this Brief, references to "Exhibit" without specification are to the Goldblatt Declaration submitted herewith.

alternative explanation for plaintiff's DTI results, concluding the most likely explanation is TBI.

Dr. Lipton's analysis was extensively buttressed in discovery. All medical files reviewed by Dr. Lipton were produced to Whirlpool. In addition to his expert report, Dr. Lipton provided, at Whirlpool's request, a detailed affidavit explaining his DTI analysis. Dr. Lipton sat for a deposition twice, and explained why alternatives to TBI cannot explain plaintiff's abnormally low anisotropy. Whirlpool medical experts spent four days evaluating plaintiff in person. Whirlpool used this time to conduct psychiatric, neurological, and neuro-psychological evaluations.

Whirlpool's purported authority is not persuasive. Whirlpool compiles a smattering of articles, and two affidavits from a Dr. Tsiouris from a completely unrelated case (we note Dr. Tsiouris was never disclosed to plaintiff, and a report from him never provided). Dr. Tsiouris's opinions have been widely rejected in both federal and state courts, and have been characterized by a federal court as, "**misleading and often entirely unsubstantiated**." *See White v. Deere & Company*, *infra.* (Exhibit L) (emphasis added). The Wintermark et al. "white paper" on which Whirlpool heavily relies is ***not*** peer reviewed, and it is not evidence of a consensus statement. Plaintiff submits herewith the Affidavit of Jennifer C. van Velkinburgh, Ph.D., which explains the criteria for "peer review" in medical literature, and explains why the Wintermark et al. "White Paper" falls short of the mark. Whirlpool's reliance on Dr. Jeffrey Brown (Def. Br. 19) is completely misplaced. Dr. Brown is not a radiologist and lacks expertise to interpret DTI/MRI.[2]

Finally, Whirlpool cites to *Brouard v. Convery P.V. Holding Corp. et al.*, a trial-level decision excluding DTI evidence. Not only is *Brouard* contrary to New York appellate authority, and nearly all authority nationally, it has also been disregarded by every court in New York faced

[2] Dr. Brown writes at page 78 of his report: "this examiner… would defer to the opinions of a Board-certified neuro-radiologist experienced in MRI with DTI interpretation regarding the clinical and 'causation' significance of the MRI with DTI that had been done." Dr. Brown is thus openly admitting he would defer to Dr. Lipton with respect to DTI.

with this issue subsequent to the decision.

BACKGROUND

Plaintiff alleges a head injury from a slip-and-fall on July 10, 2015, in a puddle caused by a leaking Whirlpool freezer. Plaintiff's kitchen is sunken one step down from her living room; when plaintiff fell, her chin hit the edge of the step up into her living room, causing her head to shoot back. Plaintiff went to the emergency room where Dr. Marcel Sheinmann sutured her chin. Two days after her fall, plaintiff called Dr. Scheinmann, complaining of continued dizziness. Dr. Scheinmann recommended that she see a neurologist "ASAP."

On July 22, 2015, plaintiff presented to neurologist Dr. Alexander Schick, who documented "trauma… slipped on wet floor – fell forward – her face and chin hit the step…" Dr. Schick diagnosed plaintiff's headaches. Plaintiff returned to Dr. Schick on August 3, 2015 (Exhibit B). As symptoms did not subside, plaintiff presented to neurologist Dr. Ellen Braunstein on April 4, and again on April 8, 2016, who documented that, since her fall, plaintiff had been experiencing dizziness, sensitivity to noise, difficulty with concentration and balance, migraine headaches and blurred vision, all symptoms of concussion. Dr. Braunstein diagnosed "concussion injury of brain," and, *inter alia*, dizziness, headaches, transient memory loss, and transient visual loss, and gave plaintiff educational materials on concussion and vertigo (Exhibit C). Dr. Braunstein referred plaintiff for an EEG, which was abnormal (Exhibit D), an ENG, which was also abnormal (Exhibit E), and for NeuroTrax testing (computerized testing that measures cognitive functioning in several domains, similar to an abbreviated neuropsychological assessment), which demonstrated plaintiff was functioning below average in the domains of memory, executive functioning and visual-spatial (depth) perception (Exhibit F).

Symptoms persisted. On the referral of her primary care physician, who was concerned with plaintiff's concussion and post-concussive symptoms, on December 22, 2016, plaintiff presented to Dr. Thomas Berk, Clinical Assistant Professor, Department of Neurology, at NYU Langone Medical Center. Dr. Berk diagnosed plaintiff with, *inter alia*, concussion, post-concussive syndrome, intractable chronic post-traumatic headache, and vertigo. Plaintiff returned to Dr. Berk in February and April 2017, and the above-noted diagnoses were unchanged. Dr. Berk referred plaintiff to a neuro-ophthalmologist as well as vestibular physical therapy, which plaintiff attended for 3½ months (Exhibit G). Plaintiff saw Dr. Berk on January 11, 2018, and was diagnosed with concussion, post-concussive syndrome, and chronic migraine. Dr. Berk's impressions indicate: "Rivka Reichmann has a diagnosis of concussion, post concussive syndrome, likely TBI in light of DTI results." Dr. Berk, Dr. Schick, and Dr. Braunstein are plaintiff's treating physicians; they were not retained in connection with litigation.

DIFFUSION TENSOR IMAGING

A comprehensive description of DTI technology is contained in Dr. Lipton's Declaration (Exhibit A). Briefly, DTI is a series within an MRI scan protocol that measures the flow of water molecules (diffusion) through the microscopic white matter fiber tracks (axons) of the brain. These axons connect brain cells (neurons) and act as the wiring of the brain that permits brain cells to communicate with one another, resulting in our cognitive abilities.

In the white matter of the normal/healthy brain, the microscopic structure of myelin, cells and membranes present parallel barriers to the free movement of water molecules. As a result, the direction of water diffusion is very uniform over very small distances and is therefore termed anisotropic. Injury can disrupt the normal structure of white matter, leading to less uniform direction of diffusion, which is said to be less anisotropic, or more isotropic. This is referred to as

"axonal injury" which is recognized within the field of brain injury medicine as the pathophysiological (injury) cause of concussive symptoms and is responsible for impairments in cognition (Eibling Declaration, Exhibit D, pp. 24, 25).

DTI measures the uniformity, or anisotropy, of water diffusion, with the degree of anisotropy expressed as fractional anisotropy ("FA"), measured on a scale from zero (completely isotropic diffusion) to one (perfectly unidirectional diffusion). DTI is far more sensitive than standard MRI in that it has the capability of identifying abnormal structure of the microscopic white matter brain tissue that standard MRI is not sensitive enough to detect.

PLAINTIFF'S DTI SCAN AND DR. LIPTON'S DIFFERENTIAL DIAGNOSIS

On October 23, 2017, plaintiff underwent an MRI of the brain with DTI at Montefiore Medical Center, which was interpreted by Michael Lipton, M.D. Within his report, which was exchanged with defendants, Dr. Lipton noted that the quantitative analysis of fractional anisotropy images from DTI demonstrated abnormally low FA within the white matter of the frontal lobes, bilaterally, of plaintiff's brain. He also noted that, while these findings were consistent with traumatic axonal injury, other causes needed to be considered (Eibling Declaration, Exhibit A).

Thereafter, Dr. Lipton prepared a report dated July 6, 2018, within which, after reviewing records from 13 different providers and, contrary to defendants' assertion, performing a differential diagnosis, Dr. Lipton ruled out alternative causes for the findings on the DTI other than the subject trauma (Eibling Declaration, Exhibit B). His conclusion: TBI is the most likely cause for plaintiff's DTI results. Dr. Lipton's report states (at p. 3):

> Although the imaging findings in Ms. Reichmann's brain are entirely consistent with and characteristic of the injury she sustained, abnormally low FA can, in general, be associated with other brain disorders. This is no different than other common MRI findings, which may be associated with more than one disorder. The process of differential diagnosis must be applied, considering all available clinical information including the presence or absence of other imaging findings, to determine whether any alternate diagnosis pertains in the case of a particular

> patient. Ms. Reichmann is a young individual who is otherwise healthy and has no history, based on the records I have reviewed including pre-injury healthcare records, of any disorder that would offer a plausible alternate explanation for the imaging abnormalities. She has no other visible brain abnormalities, which is entirely consistent with mTBI, but would be unusual in other disorders, such as demyelinating or ischemic disease. Thus, TAI [traumatic axonal injury] remains most only plausible explanation for the findings and remains entirely consistent with other features reflected in the records of Ms. Reichmann's care.

Contrary to defendants' assertions, at no time did Dr. Lipton "diagnose" plaintiff with a traumatic brain injury, either within his October 23, 2017 MRI report or his subsequent expert report.

Similarly, contrary to defendants' assertions, neither Dr. Rosenbaum, within her November 20, 2017 report detailing her findings from plaintiff's neuropsychological assessment (Eibling Declaration, Exhibit F), nor Dr. Greenwald, within his January 26, 2018 expert report (Eibling Declaration, Exhibit D), diagnosed plaintiff with having sustained a brain injury. Rather, after administering a comprehensive neuropsychological assessment, Dr. Rosenbaum reported that the findings demonstrated plaintiff was experiencing cognitive limitations. Additionally, only after reviewing all relevant records and taking into account plaintiff's lack of significant pre-morbid history did Dr. Rosenbaum opine that plaintiff's cognitive impairments were causally related to the subject fall, which was also consistent with the frontal lobe pathology identified in the DTI interpreted by Dr. Lipton (Eibling Declaration, Exhibit F, p. 16).

With respect to Dr. Greenwald, after reviewing all relevant medical records, interviewing plaintiff and taking into account the lack of significant pre-morbid history, rather than diagnose plaintiff with a brain injury, Dr. Greenwald merely highlighted that plaintiff had been repeatedly diagnosed with traumatic brain injury by her treating clinicians and that these clinical diagnoses met the diagnostic criteria established by the American Congress of Rehabilitation Medicine. He

also explained the concept of "rapid acceleration and deceleration"[3] as the mechanism by which axonal injury occurs (Eibling Declaration, Exhibit E, p. 24). With respect to the DTI, Dr. Greenwald did not use the findings to "diagnose" a brain injury. Rather, he highlighted that the location of the findings demonstrated objective evidence of axonal damage consistent with both the objective findings of Dr. Rosenbaum's neuropsychological assessment and plaintiff's subjective complaints (Eibling Declaration, Exhibit E, p. 25). Stated differently, he put together the "pieces of the puzzle" and performed a differential diagnosis leading to his opinions.

STANDARD

"The Rules of Evidence provide a liberal standard for the admissibility of expert testimony." *United States v. Dukagjini*, 326 F.3d 45, 52 (2d Cir. 2003) (citing *Daubert*, 509 U.S. at 588). As the Second Circuit clarified:

> A trial judge should exclude expert testimony if it is speculative or conjectural or based on assumptions that are 'so unrealistic and contradictory as to suggest bad faith' or to be in essence 'an apples and oranges comparison.' Other contentions that the assumptions are unfounded go to the weight, not the admissibility, of the testimony.

Zerega Ave. Realty Corp. v. Hornbeck Offshore Transp., LLC, 571 F.3d 206, 214 (2d Cir. 2009) (internal citations and quotation marks omitted). "[B]y loosening the strictures on scientific evidence set by *Frye*, *Daubert* reinforces the idea that there should be a presumption of admissibility of evidence." *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995). *Daubert* "expressed its faith in the power of the adversary system to test 'shaky but admissible' evidence, and advanced a bias in favor of admitting evidence short of that solidly and indisputably proven to be reliable." *Id.* "Once the thresholds of reliability and relevance are met, the testimony is admissible. Thereafter, any purported weakness in an expert's methodology or conclusion goes to

[3] Dr. Lipton also explains the concept of rapid acceleration/deceleration as the mechanism by which axonal injury occurs.

the degree of credibility to be accorded to the evidence, not to the question of its admissibility." *Royal Ins. Co. of Am. v. Joseph Daniel Const., Inc.*, 208 F. Supp. 2d 423, 426 (S.D.N.Y. 2002).

ARGUMENT

A. DTI Technology is Generally Accepted in the Scientific Community

Whirlpool's argument that DTI is not reliable (Def. Br. 10-16) does not get off the ground. As set forth below, Whirlpool contradicts dozens of courts holding DTI reliable and admissible, and the overwhelming weight of medical literature.

Peer-Reviewed Literature

There are literally thousands of peer-reviewed articles discussing the reliability of DTI. In addition to the peer-reviewed scientific literature cited in Dr. Lipton's affirmation and listed in his CV demonstrating the general acceptance within the scientific community of the reliability of DTI in clinical use to identify axonal injury, is a listing from Pub MED of peer-reviewed articles regarding research into DTI technology (Exhibit H). Among them, the June 2, 2011 issue of the *New England Journal of Medicine* featured an article entitled "Detection of Blast-Related Traumatic Brain Injury in U.S. Military Personnel" that not only supports the use of DTI for the investigation of TBI in American soldiers and others, but based on DTI and a two standard deviation threshold for FA to determine abnormality, discriminated soldiers with mTBI from controls. As the authors of that article stated:

> With the use of DTI, we found abnormalities consistent with traumatic axonal injury in U.S. military personnel with blast-related mild traumatic brain injury.
>
> Because DTI can be performed relatively quickly on the MRI scanners at U.S. military facilities and civilian hospitals, DTI-based assessments may be useful in diagnosis, triage, and treatment planning in clinical practice.

(Exhibit I). This article is peer-reviewed and endorsed by one of the elite journals in American medicine on the use of DTI to: 1) investigate traumatic brain injury; and 2) use as part of a differential diagnosis after the clinical diagnosis of brain injury.

American Society for Functional Neuroradiology (ASFNR)

In March 2012, a five-member sub-specialty committee (of which Dr. Lipton was a part) of the ASFNR, the governing body for neuroradiologists in the United States, published guidelines for the clinical use of DTI in the diagnosis and treatment of concussion in people with mild traumatic brain injury (mTBI) (Exhibit J). There would be no such guidelines if the ASFNR did not recognize DTI as valid, reliable and generally accepted within the scientific community.

Federal Court Authority

In *Marsh v. Celebrity Cruises, Inc.*, Case No. 1:17-cv-21097-UU, U.S. District Court, Southern District of Florida (Exhibit K), after falling and hitting her head, plaintiff was diagnosed with a mild traumatic brain injury (TBI). The plaintiff offered an expert, Dr. York, who would testify as to the results of DTI imaging and, in conjunction with a multitude of other tests and records, opine that the DTI results were consistent with the clinical diagnosis of mild TBI. The defendant moved to bar Dr. York's testimony. In denying defendant's motion, the Court rejected defendant's argument, highlighting that: 1) DTI findings and testimony have been deemed reliable and admitted by courts across the country for almost a decade; and 2) as of 2010, DTI had been the subject of 3,472 peer-reviewed papers.[4] The Court also noted that, like Dr. Lipton in the instant matter, the plaintiff's expert opinion was not based solely on the results of DTI but also his review of a number of other medical records (Exhibit K, p. 5). Finally, the Court also rejected defendant's assertion that "the DTI's acquisition of data is affected by the field's strength of the magnet and there is a lack of a standardized protocol for the acquisition and interpretation of DTI results."

[4] The Court specifically highlights the paper entitled "A Decade of DTI in Traumatic Brain Injury: 10 years and 100 articles later" of which Dr. Lipton was the lead author, and which was published in the Journal of Neuroradiology, the same article cited by Dr. Lipton in his affirmation (Exhibit A, ¶ 41).

In *White v. Deere & Company* (U.S. District Court, District of Colorado, Case 1:13 c.v. 02173, February 8, 2016) (Exhibit L), like defendants in the instant matter, relying on the Wintermark "White Paper", defendants moved to exclude testimony relative to DTI. In denying the motion, the Court rejected the Wintermark article cited by the defense, while also directly rebuking the opinions of several defense experts, including Dr. Tsiouris, whom defendants herein rely upon, as "**misleading and often entirely unsubstantiated**" (emphasis added).

> The articles cited by plaintiff appear to support the conclusion that DTI is a generally accepted diagnostic measure for TBI. One peer-reviewed article cited by plaintiff reveals the last decade of research conducted on DTI and finds that "[a] unifying theme can be deduced from this large body of research: DTI is an extremely useful and robust tool for the detection of TBI-related brain abnormalities…Another peer-reviewed article cited by the plaintiff states that the "overwhelming consensus of a substantial body of scientific inquiry supports DTI for detecting pathology in [mild TBI ("mTBI")] patients… and directly challenges the criticisms of DTI proffered by defendants' expert, Dr. Hal Wortzel. Id at 2 ("**the misleading and often entirely unsubstantiated opinions and positions of Wortzel, Tsiouris and Filippi (2014), in opposition to diffusion tensor imaging (DTI) as a useful measure in mTBI, are at odds with the clear consensus of scientific literature regarding [mTBI], its clinical assessment, and natural history") (emphasis added)**. The court notes that the November 2014 research paper cited by defendants (Wintermark White Paper) acknowledges that "there is evidence from a group analyses that DTI can identify TBI-associated changes in the brain across a range of injury severity, from mild to severe TBI. Evidence also suggests that DTI has the sensitivity necessary to detect acute and chronic TBI-associated changes in the brain, some of which correlate with injury outcomes."…Thus, the Court finds that defendants have not shown that the November 2014 research paper, or other evidence, establishes that DTI is an unreliable technology to detect mild TBI-associated changes in the brain

In *Roach v. Hughes*, Civil Action No. 4:13-CV-00136-JHM, 2016 WL 9460306, at *3 (W.D. Ky. Mar. 9, 2016) (Exhibit M) the Court denied defendant's motion to preclude evidence of DTI, finding that it was not the only source of information Dr. Benson used to diagnose TBI. Rather, "Dr. Benson pairs the neuroimaging results with the neuropsychological assessment, which helps determine the cognitive deficiencies [the plaintiff] suffers from, to determine the presence of brain damage. Dr. Benson readily admits that DTI, like any other imaging technique,

'does not reveal the etiology of a particular pathology all by itself. DTI reveals damage to axons. DTI is used as other imaging modalities are used—to add important information regarding a differential diagnosis. In the case of mTBI, DTI is used in conjunction with clinical history, physical examination, and other MRI sequences/scans.' Many of Defendants complaints go to the weight that the jury may afford to the evidence offered, not the admissibility of the evidence, and can be adequately addressed through cross-examination".

In *Andrews v. Patterson Motor Freight, Inc.*, Case No. 6:13 cv 814 (U.S.D.C., W.D. La. 2014) (Exhibit N), plaintiff proffered the testimony of Dr. Eduardo Gonzalez-Toledo, who administered an MRI with DTI and interpreted the same to show abnormal pathology consistent with traumatic brain injury. Defendants moved to preclude Dr. Gonzalez-Toledo, on the grounds that DTI was not widely accepted for the diagnosis of traumatic brain injury. In support of their argument, defendants relied upon "*Guidelines for the Ethical Use of Neuroimages in Medical Testimony*", the same article relied upon by defendants herein (Eibling Declaration, Exhibit H). The Court denied defendants' motion, holding that plaintiff had submitted sufficient evidence pursuant to *Daubert* to show the reliability of DTI, specifically that it had been subject to peer review and publication, tested and had a low error rate and as such, was a generally accepted method for detecting abnormal pathology. The Court also noted that testimony pertaining to the findings of DTI had been admitted by several courts. *See, e.g.*, *Ruppel v. Kucanin*, 2011 WL 2470621 (N.D. Ind.) (Exhibit O); *Booth v. Kit*, 2009 WL 4544743 (D.N.M.) (Exhibit P); *Hammar v. Sentinel Ins. Co., Ltd.*, No. 08-019984 (Fla. Cir. Ct. 2010) (Exhibit Q).

In *Ruppel* (Exhibit O), pursuant to Fed. Rules of Evid. 702, defendant sought to preclude testimony from Dr. Randall Benson relative to his interpretation of DTI, arguing specifically that Dr. Benson's opinion regarding plaintiff's concussive injury was not reliable because he used DTI

to reach his conclusion. Under a *Daubert* analysis, the Court issued a ruling denying the defendant's motion to exclude DTI evidence, complete with a lengthy discussion of DTI and specifically Dr. Benson's use of DTI. The Court stated that "DTI and FA quantification based on comparative scans appear to be reliable methods for Dr. Benson to arrive at his expert opinion of both Ruppel's diagnosis of diffuse axonal injury and the cause of that injury." The Court made the following statements regarding DTI's general acceptance in the medical community:

> "there have been numerous validation studies, published in peer reviewed journals, on the use of DTI to detect diffuse axonal injuries."
>
> "DTI is regularly used as a diagnostic tool at the Detroit Medical Center and at other locations throughout the country"
>
> "the United States Army Telemedicine and Advanced Technology Research Command sponsored a 'Diffusion MRI TBI Roadmap Development Workshop' at which it was acknowledged: 'DTI has detected abnormalities associated with brain trauma at several single centers.'"
>
> "approval for marketing by the FDA indicates that its effectiveness was determined pursuant to 21 U.S.C. § 360c(a)(3)(A)"
>
> "DTI has been accepted within the medical community." "Importantly, as discussed below, there are many articles published in peer-reviewed publications that cover the effectiveness of DTI in detecting mild TBI."
>
> "the evidence shows that DTI and analysis of white matter in DTI images are generally accepted methods for determining mild TBI."

The Court further found that DTI was demonstrably reliable through the remaining *Daubert* factors, independent of its general acceptance in the medical community.

In *Booth v. Kit* (Civ. No. 06-1219 JP/KBM (D.N.M. March 23, 2009) (Exhibit P)), the U.S. District Court for the District of New Mexico denied the defendant's motion to strike, limit, or exclude expert testimony from Dr. Orrison that, in part, relied on DTI testing. The Court held that the expert's testimony was admissible under Rule 702 because the reasoning and methodology

underlying the testimony was scientifically valid, had been sufficiently tested, peer reviewed, lacked a high error rate, and was generally accepted in the scientific community.

In *Chiulli v. Newbury Fine Dining* (Civ. No. 10-10488 JLT) (D. Mass. 2012), out of the District Court of Massachusetts, the defense moved to preclude Dr. Benson from testifying as to an individual's DTI results, arguing that DTI was not generally accepted for that purpose and that Dr. Benson's methodology was not reliable. Judge Tauro denied the motion (Exhibit R). Similarly, in *Shannon v. Columbia River Basin Railroad,* the Western District of Washington denied defendants' motion to preclude Dr. Wu from testifying about the results of DTI imaging (Exhibit S).

State Courts Applying *Daubert* Standard

Numerous state-court decisions applying a *Daubert* standard have similarly held DTI admissible, in thorough and well-reasoned opinions. *See*:

- *Vizzo v. Fairfield Bedford, LLC* No: fst-cv12-6015703-s, Connecticut Superior Court, November 2, 2016 (Exhibit T), denying motion to exclude DTI evidence.
    - Defendant, just as Whirlpool herein, relied on the Wintermark et al. "White Paper" and article "*Guidelines for the Ethical Use of Neuroimages in Medical Testimony*," and retained the same expert as Whirlpool herein, Dr. Lawrence Tanenbaum.
    - In opposition, plaintiff submitted the affidavit of Dr. Benson who, in an understatement, took to task the opinions of Dr. Tannenbaum (Exhibit U).
    - Like Dr. Lipton in the instant matter, Dr. Benson conceded that standing alone, DTI could not diagnose brain injury but rather, was used to identify abnormalities in white matter brain tissue that could be correlated with a particular ideology. Additionally, citing to the ASFNR Guidelines (Exhibit J), the plaintiff highlighted that DTI technology was used within the clinical setting throughout the country. Finally, plaintiff highlighted that DTI technology was reliable because it had been tested, peer-reviewed, had a low error rate and was developed independent of litigation.
    - With respect to the "white paper", the plaintiff highlighted the inconsistent position taken by Dr. Wintermark who, within his paper, seemed to opine that DTI should not be used in clinical practice, while at the same time endorsing its use in clinical practice within the foreword to a publication entitled "*Diffusion Weighted and Diffusion Tensor Imaging*", which included a chapter written by Dr. Lipton entitled "Diffusion Imaging for the Assessment of Traumatic Brain Injury". Specifically, within the foreword

to the book, Dr. Wintermark stated that:

> DTI is a powerful technique that has multiple potential applications including neurosurgical guidance in the diagnosis of mild traumatic brain injury….. There is no doubt that radiologists interpreting neuroimaging studies should read this book and have it at the ready, not only for reference, but also to refresh their memory about DWI and to learn ways to incorporate DTI in the care of their patients. (Exhibit V)

- The Court highlighted the affidavits submitted by the leading experts in the field of DTI technology, including Dr. Lipton, who all not only use DTI within clinical practice, but who have authored numerous peer-reviewed articles (Exhibit W).

- Utilizing a *Daubert* standard, the Court rejected the defendants' argument that diffusion tensor imaging should be barred, finding that the grounds for defendants' motion went more to the weight of the evidence rather than the admissibility of it.

- In *Ebel v. Apache* (Case No. D-101-cv-2012-01210, N.M., 1st Jud. District), defendants moved to preclude the testimony of Dr. Randall Benson. After hearing oral argument, the New Mexico court denied the defendant's application, finding that is was "not well-taken" (Exhibit X). Also using a *Daubert* standard, similar results were reached in the Michigan matter of *Ikola v. Wright* (Exhibit Y) the Wisconsin matter of *Lewis v. Principal Life Insurance Co*. (Exhibit Z); and the California matter of *Gutcher v. Toyota Motor Sales, et al.* (Exhibit AA, pp. 88- 95).

- In *Zawaski v. Gigs, LLC* (Suffolk Superior Court, Civil Action No. 2008-2380, November 4, 2010), plaintiff sought to admit results of DTI testing that showed axonal damage. The defense argued that DTI was not sufficiently reliable to support a clinical diagnosis of mTBI. The Court denied defendants' motion, highlighting the numerous peer-reviewed articles establishing that DTI was reliable for detecting axonal damage, along with that fact that every court in the country had rejected either *Daubert* or *Frye* challenges to DTI testimony (Exhibit BB).

- In *Whilden v. Cline*, District Court, Jefferson County, Colorado, Case No. 08CV4210 (May 10, 2010), also using a *Daubert* standard, a Colorado trial court denied defendant's motion in limine to bar the testimony of Dr. William Orrison, holding that DTI technology was sufficiently reliable and scientifically accepted so as to be of benefit to the jury. Specifically, the Court stated:

> This court is convinced that [DTI] produces predictable, reproducible results and accurately images the portions of the brain to which it is applied. For these purposes, it is sufficiently accepted in the scientific and medical communities. It has been the subject of

> a substantial number of published studies and article, including peer reviewed articles (internal citations omitted) (Exhibit CC).

The *Whilden* Court did note that it would have serious concerns about the appropriateness of diagnosing mTBI as the cause of abnormality based solely on the results of the DTI. However, the Court understood that, like the instant matter with Dr. Lipton, Dr. Orrison's opinion was not based solely upon his interpretation of the DTI, but coupled with other evidence, including the plaintiff's history. *See also Rye v. Kia Motors America, Inc.*, Case No. 07-701204-NP (Circuit Court, Wayne County, Mich., Feb. 16, 2010) (Exhibit DD).

New York State Courts Applying *Frye* Standard

In New York, numerous courts applying a *Frye* standard – arguably more stringent than *Daubert*[5] – have similarly held DTI evidence admissible. *See*:

- *Lamasa v. Bachman*, 56 A.D.3d 340 (1st Dept., 2008), affirming trial court decision allowing DTI evidence and Dr. Lipton testimony in TBI case. The trial court observed:

> DTI is an imaging technique used to study the random motion of hydrogen atoms within water molecules in biological tissue (e.g., brain white matter) and spatially map this diffusion of water molecules, in vivo. DTI provides anatomical information about tissue structure and composition. Changes in these tissue properties can often be correlated with processes that occur, among other causes, as a result of disease and trauma. 8 Misc.3d 1001 (A).

The First Department affirmed.

- *Aravindakshan v. Martello* (Sup. Ct., Nassau County, Index No. 11984/2012), on referral from a treating concussion specialist, plaintiff underwent an MRI with DTI at Montefiore Medical Center, which was interpreted by Dr. Michael Lipton. The Court granted plaintiff's motion to preclude the defense expert from testifying that:

> DTI studies are not accepted in the field of neuroradiology as a method to diagnose individual patients with a traumatic brain injury;
>
> DTI studies are not endorsed for clinical diagnosis or prognostication in the individual patient with suspected traumatic brain injury by the American College of Radiology Head Injury Institute, the American Society of Neuroradiology or the American Society of Functional Neuroradiology; and
>
> There is no generally accepted standard with regard to the FA levels throughout the various structures of the brain.

[5] "[B]y loosening the strictures on scientific evidence set by *Frye*, *Daubert* reinforces the idea that there should be a presumption of admissibility of evidence." *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995).

Notably, the *Aravindakshan* court granted this motion one month after the decision in *Brouard*. The Court also precluded the defense expert from relying upon the Wintermark "White Paper" (Exhibit EE).

- *Caramanica v. Rhim* (Sup. Ct., New York County, March 23, 2018) (Exhibit FF), holding DTI admissible under *Frye* and collecting cases; declining to follow *Brouard*, as "**one anomalous decision**" insufficient to overcome the weight of precedent and peer reviewed medical literature (Exhibit FF, p. 8) (emphasis added).

- *Barney-Yeboah v. Metro-North Commuter Railroad* (Sup. Ct., New York County, Index No. 103354/2010) (Exhibit GG), denying defendants' motion to preclude DTI, rejecting defense argument that a new consensus had overtaken prior case law, and rejecting defense contention that Dr. Lipton was an "outlier (Exhibit DD, pp.14-15). The Court took judicial notice of the fact that DTI technology had been found to be scientifically reliable in numerous judicial proceedings and was generally accepted within the medical community (Exhibit GG, pp. 13-14).

- *See also Konstantinov v. MTLR Corp.* (Sup. Ct., New York County, Index No. 103354/2010) (Exhibit HH), where the Court took judicial notice of the general acceptance and admissibility under *Frye* of evidence relating to DTI, rejecting the holding in *Brouard* and the Wintermark "White Paper" as being "unpersuasive in its conclusion that there was insufficient evidence that DTI can be used for routine clinical purposes".

Prior to *Brouard*, every court has denied attempts to exclude testimony regarding DTI technology. See *Casas v. Consolidated Edison Company of New York* (Sup. Ct., New York County, Index No. 115106/2014, March 24, 4017) *(*Exhibit II) (DTI has been recognized as reliable and generally accepted within the scientific, as well as the legal, community and as such did not even warrant a *Frye* hearing. *See also Klipper v. Liberty Helicopter* (Sup. Ct., New York County, Index No. 110711/03, January 12, 2015) (Exhibit JJ) ("The scientific articles submitted by plaintiffs, coupled with the fact that numerous courts in various jurisdictions, as well as in this state, have admitted DTI results into evidence, establish that there is general acceptance of DTI in the medical community as a means of diagnosing traumatic brain injury"). See also *Melendez v. Marten Transport Ltd.* (Sup. Ct., Rockland County, Index No. 34148/12, November 30, 2015) (Exhibit

KK);[6] *Girgs v. Snapple Distribution Corp. and Mr. Natural Inc.* (Sup. Ct. Nassau County, Index No. 510/98, May 22, 2014) (Exhibit LL) (Court noted that the use of DTI was the subject of sufficient peer-reviewed articles appearing in respected scientific journals, including an article entitled "*Detection of Blast-Related Traumatic Injury in U.S. Military Personnel*" that was published in The New England Journal of Medicine (see Exhibit I), as well as the fact that Dr. Lipton's control group had been peer reviewed. The Court also noted that, like the instant matter, the DTI was not the sole evidence to be produced at trial but rather, just part of the evidence); *Sullivan v. Walters* (Sup. Ct. Nassau County, Index No. 6110/05, July 9, 2014) (Exhibit MM) ("Other factors that contributed to the results of the plaintiff's DTI speak to causation which may be evaluated and resolved by a jury. They do not speak to the reliability of the test itself. Similarly, the defendant's expert'[s] [**Dr. Tsiouris, upon whom defendants herein rely]** disagreement with the underlying significance of the plaintiff's DTI readings merely provides information for a jury to process"); *Velez v. Merejo* (Sup. Ct., New York County, Index No. 115897/08, Nov. 6, 2014) (Exhibit NN); S*iracusa v. City Ice Pavilion, LLC*, 57 Misc. 3d 267, N.Y.S. 3d 290 (2017).

State Courts Nationally Applying *Frye* Standard

Jurisdictions outside New York applying the *Frye* standard have also universally held that DTI science is generally accepted.

In *Peach v. RLI Insurance Company*, No. 17-2-16348-1 SEA (Sup. Ct., Washington), the Court denied defendants' motion to preclude holding that:

> This Court finds that the science and methodology underlined in diffusion tensor imaging (DTI) is well accepted in the medical and scientific community;

[6] The Court's decision was rendered from the bench and is contained within a lengthy transcript. Only the relevant portions are annexed hereto. Should the Court desire the full transcript, the same will be provided upon request.

> The Court further finds any difference of opinion among the experts, with regards to the application of DTI to determine whether a patient has mild traumatic brain injury (mTBI), is a matter of weight rather than admissibility;
>
> The Court finds that Dr. Raji or Dr. Stobbe are not relying exclusively on the DTI or ASL findings to make a mTBI diagnosis; other evidence also supports a diagnosis of mTBI. This is consistent with the medical community's approach. Admissibility of this testimony and the tests are consistent with decisions in other jurisdictions and peer reviewed articles (Exhibit OO).

In *Hammar v. Sentinel Insurance Company, Ltd.*, Civil Action No. 08-019984 (Cir. Ct., Florida) Judge Barton wrote:

> DTI of the brain is a proven and well-established imaging modality in the evaluation and assessment of normal and abnormal conditions of the brain. DTI demonstrates evidence of traumatic brain injury pathology and can reveal abnormalities that are not visible on standard MRIs…
>
> DTI is generally accepted by the medical community, FDA approved, peer reviewed and approved, and a commercially marketed imaging modality which has been in clinical use for the evaluation of suspected head traumas including mild traumatic brain injury. (Exhibit Q)

See also Andrus v. Mark Russell Fulgham, Case No. 040904243 (3rd J.D. Utah) (Exhibit PP); *Hansen v. Crane*, File Number 62-CV-10-2435 (2nd J.D., Minnesota) "it's clear to me that the technology involving DTI is something that is not novel to the medical industry. It is not novel science, has been around for maybe some twenty years and is relied upon by medical professionals in a number of settings" (Exhibit QQ); *Craffey v. Embree Construction* (Norfolk Civil Action No. 13-1232-A (Sup Ct., Mass.) (Exhibit RR, p. 7); *Hyman v. Chang, M.D.*, File Number 62-CV-11-9418 (2nd J.D. Minnesota) (Exhibit SS); *Nordstrom v. Fleet Farm of Menomonie, Inc.*, File Number 82-CV-11-5842 (10th J.D. Minnesota) (Exhibit TT);

In *Sworin v. Harris* (Case No. 08-05836-CA, Cir. Ct., Florida, Collier County, Apr. 4, 2014) (Exhibit UU), the Court denied the defendant's motion to exclude DTI evidence, stating that "DTI is not new or novel science," it is FDA approved, reimbursable by insurance companies, and

used clinically throughout the country and world, and it passes the Daubert standard for admission. The Court stated the following:

> DTI has been subjected to peer review by the National Institute of Disability and Rehabilitation Research (NIDRR), which is a division of the U.S. Department of Education.
>
> Dr. Benson did not develop his opinions regarding DTI for the purpose of testifying. Rather, Dr. Benson has submitted peer reviewed articles and testimony to the United States Congress that support the use of DTI for the diagnosis of mTBI. Dr. Benson's anticipated trial testimony concerning DTI and its validity and reliability have grown naturally and directly out of research.
>
> DTI is generally accepted in the relevant scientific community for diagnosing white matter damage. DTI is demonstrably reliable, as the methodology described by Dr. Benson is not only peer reviewed but also inherently reliable based upon statistics.
>
> DTI of the brain is a proven and well-established imaging modality in the evaluation and assessment of normal and abnormal conditions of the brain. DTI demonstrates evidence of traumatic brain injury pathology and can reveal abnormalities that are not visible on standard MRIs.

Plaintiff can cite to and attach many more decisions, all recognizing the admissibility of DTI, but will refrain from doing so on the grounds that, presumably, plaintiff has made her point. Notably, in every case, the defendants submitted affidavits of experts who raised objections similar to those raised by defendants herein. Because they all fail to acknowledge the plethora of peer-reviewed articles accepting DTI as valid, as well as universal judicial acceptance of DTI as generally accepted science, every attempt at preclusion, other than *Brouard*, an anomaly, has failed which, presumably, is why defendants can only cite to this one decision where defendants' position was credited and testimony regarding DTI was precluded.

B. Whirlpool's Authority – the Wintermark "White Paper," the Emory Conference Paper, and the RSNA Position Statement – are Not Reliable or Persuasive

In support of this application, defendants attempt to convince this Court that the thousands of peer-reviewed articles on DTI are outdated and that all of the judicial decisions nationwide,

both federal and state, are wrong because they "have not comprehensively addressed the emerging scientific consensus" which holds that there is insufficient evidence that DTI technology is reliable. In addition to *Brouard*, defendants cite to: 1) the 2014 White Paper entitled *Imaging Evidence and Recommendations for Traumatic Brain Injury: Advanced Neuro- and Neurovascular Imaging Techniques"*; 2) "*Guidelines for the Ethical Use of Neuroimages in Medical Testimony: Report of a Multidisciplinary Consensus Conference" (*Eibling Declaration, Exhibit H), which was co-authored by Dr. Sze after the 2012 Conference at Emory University; and 3) 2018 Radiological Society of North America Position Statement. As further discussed below, for their own reasons, none of them supports defendants' position.

The White Paper

Whirlpool relies heavily on a "White Paper" entitled, "*Imaging Evidence and Recommendations for Traumatic Brain Injury: Advanced Neuro- and Neurovascular Imaging Techniques" (*Eibling Declaration, Exhibit I*)*. Among its authors are Dr. Max Wintermark and Dr. Apostolos Tsiouris, whose affidavits defendants rely upon herein. As an initial matter, the referenced "White Paper" itself is ***not*** peer reviewed, and accordingly, should be given no weight by the Court. Plaintiff submits herewith the Affidavit of Jennifer C. van Velkinburgh, Ph.D., explaining the criteria for "peer review" in medical literature, and explaining why the Wintermark et al. "White Paper" falls short of the mark.

Like Dr. van Velkinburgh, within his affirmation, Dr. Lipton exposes the evidentiary flaws of the referenced White Paper, including the fact that the authors disregarded all accepted parameters with respect to research and publishing, as well as the fact that it misrepresents the state of medical science regarding DTI. He also highlights that the paper's inclusion criteria of other articles wholly omits thousands of peer-reviewed articles pertaining to the use of DTI in the

field of brain injury medicine.

Moreover, on January 16, 2015, Max Wintermark, M.D., testified in a deposition in the matter of *Gunderson v. Mitch's Towing, Inc.,* LACV026353 (Iowa Dist. Ct.) (a copy of Dr Wintermark's deposition transcript is annexed hereto as Exhibit VV). Of note, Dr. Wintermark testified that he has virtually no current knowledge of DTI (pp. 27-38) and that he had no role in authoring the section of the paper pertaining to the use of DTI, as it was written by a Dr. Whitlow (pp. 37-38). Moreover, not only does Dr. Wintermark appear to lack knowledge regarding Dr. Whitlow's qualification to write on DTI, nowhere does the article reflect any such information at all regarding Dr. Whitlow's training or experience in quantitative DTI. This is in great contrast to Dr. Lipton's extensive list of DTI publications, as well as the other cited publications.

With respect to his paper and its credibility as a peer-reviewed, scientific article, Dr. Wintermark admitted that it was not, nor was it held to the same standards of publication (p. 44). Rather, Dr. Wintermark admitted that it was merely a survey of medical literature on DTI and that he did not know the paper's literature inclusion or exclusion criteria (p. 41).[7] The paper also used outdated evidentiary standards, yet Dr. Wintermark had no idea why (pp. 39-40). Additionally, even the purported organizational endorsements that Dr. Wintermark touts are a likely sham because when challenged, Dr. Wintermark struggled to substantiate any such organizational endorsement (pp. 46-50).

Dr. Wintermark concedes that his paper was compiled solely from a selective literature review and omitted peer-reviewed literature endorsing DTI for assessment of consequences of mild traumatic brain injury/concussion. In reality, rather than a well-substantiated professional pronouncement, Dr. Wintermark's paper is a poorly-informed opinion piece, with no authority to

[7] It clearly did not include any of the peer-reviewed literature referenced throughout this brief.

invalidate the extensive current literature it omitted, let alone the judicial precedents discussed above.

The 2012 Emory Conference

Defendants also rely upon a conference at Emory University in 2012 after which a paper (sometimes referred to as the Emory paper or article) was published entitled "*Guidelines for the Ethical Use of Neuroimages in Medical Testimony: Report of a Multidisciplinary Consensus Conference"* (Eibling Declaration, Exhibit H). One of the promoters of the conference and co-authors of this paper was Dr. Gordon Sze. Like Dr. Wintermark, Dr. Sze sat for a deposition during which his testimony cast significant doubts on the credibility of the contents of this paper (Exhibit WW, Sze deposition transcript, May 5, 2017):

a. He does "not really" work with quantitative DTI. (p.15);
b. The invitation list for the Emory Conference was created by the co-authors of the paper and was not open to all the experts in the field (pp.18-19, 28);
c. The meeting omitted several prominent experts in the field of quantitative DTI including [Erin] Bigler, Andrew Walker, William Orrison and Michael Lipton. (pp.26-28);
d. **The position in 2011 that quantitative DTI was not ready for "prime time" appears to have been driven by John Tsiouris, MD**[8] Hal Wortzel, MD [neither of whom works with quantitative DTI and both of whom work for the defense in mTBI cases] **and was not based upon any independent scientific research** (pp. 22-25,40-41, emphasis added);
e. The Emory paper was not intended as a scientific paper. (p. 115);
f. The consensus paper was not a consensus of the American Society of Neuroradiology, the Emory Department of Bioethics, or any other professional group (pp. 39-40, 56);
g. **The White Paper does not advocate excluding DTI evidence** (pp.71-73, emphasis added);
h. Neither the Meltzer paper nor the papers that arose from the Montreal Symposium reflects "bench research" that involved collecting fresh controls and patients with TBI; they were not meta-analyses (pp. 86-89); and

[8] This is the same Dr. Tsiouris upon whose affidavits defendants herein rely.

i. That within any peer-reviewed journal there are articles that have different levels of evidence. Within the Oxford Centre for Evidence Based Medicine, there are classifications that are more persuasive than others. Even an article with the lowest level of evidence would have to pass "peer review" (pp. 112-115).[9]

In light of the above, the paper relied upon by defendants does not support their position. Rather, defendants have misrepresented not only the state of the science of DTI but also the manner it is used by clinicians who evaluate and diagnose TBI and mTBI in particular.

The Radiological Society of North America (RSNA) Position Statement

The final piece of evidence relied upon by defendants is a purported position statement published by the RSNA (Eibling Declaration, Ex. K). Like defendants' other evidence, this too misrepresents the state of science and DTI. To begin with, the position statement references that the evidence supporting the content is presented in two articles: "*Imaging Evidence and Recommendations for Traumatic Brain Injury: Advanced Neuro and Neurovascular Imaging Techniques*" and *"Imaging Evidence and Recommendations for Traumatic Brain Injury: Conventional Neuroimaging Techniques*". As discussed earlier, one of these is the Wintermark White Paper, and the other is an offshoot, both co-authored by Drs. Wintermark and Tsiouris, the latter upon whom defendants rely. As noted above, at his deposition, Dr. Wintermark admitted he possesses no knowledge regarding DTI, among other admissions casting doubt on the credibility of the article. As for Dr. Tsiouris, in addition to being a notorious defense expert, his opinions have not only been rejected, but were characterized by a federal judge as providing "**misleading and often entirely unsubstantiated**" opinions. *See White v. Deere & Company*, supra (Exhibit L).

[9] The references to Dr. Sze's deposition testimony is taken from *Plaintiff's Supplemental Objection to Defendant's Motion in Limine Re: Dr. Randall Benson and Diffusion Tensor Imaging*, Stewart Casper, Esq. of Casper & de Toldeo, LLC, *Vizzo v. Fairfield Bedford LLC, supra* (Exhibit T).

Further proof that the contents of the position statement is a sham is found in the fact that this highlighted quote "*at present, there is insufficient evidence supporting the routine clinical use of these advanced neuroimaging techniques for diagnosis and/or prognostication at the individual patient level"* (Eibling Declaration, Exhibit K, bullet point 5) is lifted directly from the Wintermark White Paper (Eibling Declaration, Exhibit I, p. E3). If the White Paper lacks credibility and was never intended to advocate for the exclusion of DTI (Exhibit WW, pp. 71-73), then how can defendants argue that the RSNA position statement does.

As per Dr. Lipton, the RSNA position statement is nothing more than an extract from information provided on a section of the RSNA website for the media; this "position statement" is nowhere to be found in the portions of the website intended for professional radiologists.

The final comment to be made about this position paper is that even if accepted for more than the sham that it obviously is, the recommendation is that DTI is not to be used for the "diagnosis" of an individual patient. As highlighted numerous times throughout this brief, as well as by numerous judges who have denied defendants' applications nationwide, neither Dr. Lipton, nor any other witness using DTI technology, uses DTI to "diagnose" a brain injury. Rather, the clinical diagnosis was made by treating physicians, and the DTI was solely used to identify abnormal pathology which, after doing a comprehensive differential diagnosis, Dr. Lipton causally related to the subject accident.

C. Whirlpool's Remaining Arguments Lack Merit

1. Dr. Lipton Does Not Use DTI as a Stand-Alone Test to Diagnose TBI

To the extent Whirlpool argues "DTI is not a reliable tool for ***diagnosing TBI in individual patients***" (Def. Br. 10, emphasis added),[10] this misrepresents Dr. Lipton's opinion. Dr. Lipton

[10] This is a consistent theme in Whirlpool's brief. *See also*, Def. Br. 10 (opposing, "Use of DTI to Diagnose TBI in Individual Patients"); *id.* 12 ("concerns over the use of DTI to diagnose TBI in individual patients," at Emory

explicitly opines that plaintiff's DTI results are consistent with TBI, but **insufficient** to diagnose. It is the differential diagnosis, taking the DTI together with plaintiff's medical history and the clinical context, which leads to the opinion that TBI is the most likely explanation for plaintiff's low anisotropy.

2. FA Values for Plaintiff's Entire Brain are Not Relevant

Whirlpool argues (Def. Br. 16) that Dr. Lipton only supplied anisotropy data for one region of plaintiff's brain, rendering the analysis unreliable. Whirlpool presents no binding authority for this point, only one doctor's opinion. Moreover, Dr. Lipton also previously explained that FA values could be obtained on a disc from Montefiore Medical Center (an authorization for which defendants were provided). Additionally, the variations from the control were shown three different ways in the report that was marked as deposition Exhibit 4 -- in a grid of images, a bar graph and a chart showing the values for different regions of the brain. While defendants annex a copy of Dr. Lipton's report (Eibling Declaration, Exhibit A), they did not annex the entire report. Annexed hereto as Exhibit YY is the omitted portion of the report.

Whirlpool's attack on the adequacy of Dr. Lipton's practices is absurd. Dr. Lipton not only adheres to the ASFNR guidelines for administering DTI to assess mTBI – he literally ***wrote*** those guidelines, as a member of the ASFNR sub-committee which published them (see Exhibit J).

3. Underlying Control Group Data are Irrelevant

Whirlpool argues (Def. Br. 16-18) that Dr. Lipton's study is not verifiable because Whirlpool cannot evaluate underlying information on the control group used to evaluate plaintiff's anisotropy. Whirlpool does not explain why it needs this information, nor what specific information it is talking about, and we are aware of no requirement that an expert provide

Conference); *id*. 13 (quoting Wintermark et al. White Paper: "DTI can [not] be used for routine clinical diagnosis and/or prognostication at the individual patient level); *id*. 14 (quoting substantially similar RSNA statement).

underlying data on all subjects used in scientific analysis or research that is the basis of an opinion. Moreover, Whirlpool never requested this information in discovery – not from plaintiff, not from anyone. The information Whirlpool now, for the first time, requests, does not belong to Dr. Lipton – who would be prohibited from disclosing it, even if he were inclined; it belongs to Montefiore Medical Center, as plaintiff repeatedly disclosed to Whirlpool in discovery. That being said, during Dr. Lipton's August 29, 2018 deposition, as well as within an affirmation previously provided to defendant, Dr. Lipton has previously explained the protocol relative to the gathering and screening of the control group. That part of his prior affirmation is contained within his affirmation submitted herein with references to his deposition transcript (Exhibit XX).

4. Dr. Lipton Reliably Excluded Alternative Explanations for Plaintiff's DTI Results

Whirlpool argues (Def. Br. 18-20) that Dr. Lipton did not reliably exclude alternative explanations for plaintiff's low anisotropy. Dr. Lipton explained in his expert report, in his affidavit, and at his deposition(s) that he carefully reviewed plaintiff's medical history for alternative explanations for plaintiff's DTI scan results, and found no reasonably plausible alternative to TBI. Whirlpool has never offered an expert opinion supporting any alternative explanation for plaintiff's low anisotropy, and even if Whirlpool did, that would not be a reason to exclude Dr. Lipton, but only to submit the issue to a jury.

CONCLUSION

Defendants' motion to preclude DTI evidence and related opinions and testimony should be denied in its entirety.

Dated: Mohegan Lake, New York
March 17, 2020

Kenneth B. Goldblatt

Kenneth B. Goldblatt, Esq.